UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

STEVEN A. SALVO, Plaintiff, v. PERRIGO COMPANY, PLC, PERRIGO RESEARCH AND DEVELOPMENT CO., and CVS HEALTH CO., Defendants.	:	Civil Action No: **COMPLAINT AND JURY DEMAND**

Plaintiff Steven A. Salvo, by and through his undersigned attorneys, as and for his Complaint against Defendants Perrigo Company, PLC, Perrigo Research and Development Co. (collectively, "Perrigo") and CVS Health ("CVS") (collectively, "Defendants"), hereby alleges the following, upon information and belief, except as to the allegations specifically pertaining to himself, which are based on personal knowledge:

NATURE OF THE ACTION

1. This lawsuit concerns the manufacturing and distribution, by the Defendants, of Ranitidine – the generic form of Zantac - designed to decrease the amount of acid created by the stomach, thus treating heartburn and related conditions. Ranitidine was ingested daily by Mr. Salvo, in the amount of 300 mg. per day for approximately five years. The Ranitidine taken by Mr. Salvo contained dangerously high levels of N-nitrosodimethylamine ("NDMA"), a potent carcinogenic impurity. These NDMA levels exceed the U.S. Food and Drug Administration's permissible daily limits for the carcinogen by *thousands* of times. NDMA is listed as a "priority toxic pollutant" in federal regulations. See 40 CFR 131.36.

2. On September 13, 2019, the FDA issued a statement that deadly NDMA was found in medications containing Ranitidine. The FDA's notice stated that "NDMA is classified as a probable human carcinogen based on results from laboratory tests." Since then, the FDA's own testing "has found unacceptable levels of NDMA in samples of Ranitidine."

3. The FDA has previously established a permissible daily intake limit for NDMA of 96 nanograms. But the Ranitidine sold at CVS, which was manufactured by Perrigo, was found to contain 2,520,311 nanograms of NDMA. This was established by testing conducted by Valisure[1], an FDA-registered online pharmacy, currently licensed in 38 states and an analytical laboratory that is ISO 17025 accredited by the International Organization for Standardization. Valisure notified the FDA of its findings.

4. Defendants had actual or constructive knowledge that Ranitidine contained NDAMA, a carcinogenic poison.

5. Nevertheless, Perrigo and CVS marketed Ranitidine as a safe and effective product.

6. Indeed, despite the fact that CVS has been aware, since in or about September 2019, that Zantac and Ranitidine contained dangerous levels of NDMA removed from its shelves all non-prescription varieties of Zantac, it nevertheless allowed prescriptions to continue to be filled for Ranitidine until in or about June 2020.

7. Mr. Salvo continued to refill his prescriptions for Ranitidine from CVS until in or about June 2020 – nine months after it was learned that Ranitidine contained dangerous levels of NDMA.

8. CVS never warned Mr. Salvo to stop taking prescription Ranitidine. Indeed, CVS

[1] Valisure, Valisure Citizen Petition on Ranitidine 1 (2019), https://www.valisure.com/wp-content/uploads/Valisure-Ranitidine-FDA-Citizen-Petition-v4.12.pdf (hereinafter "Valisure Petition").

dispensed Ranitidine to Mr. Salvo in or about March 2020, when CVS gave Mr. Salvo a 90 day supply of Ranitidine. It was not until May 2020, when Mr. Salvo called CVS to refill his prescription for Ranitidine, that CVS informed him that the drug was not being manufactured anymore and he should ask his doctor for a substitute. Even at that time, CVS did not inform Mr. Salvo that Ranitidine contained poisonous carcinogens.

9. As a result of CVS's gross negligence and misconduct, Mr. Salvo continued taking Ranitidine for approximately nine months after CVS knew the FDA had declared it to contain unsafe levels of a toxic carcinogen.

10. When Mr. Salvo went to CVS and purchased Ranitidine, he expected that the medication would be safe for the purpose for which it was purchased. He did not expect, and Defendants did not disclose, that the medication contained a poisonous, carcinogenic poison.

11. As a proximate result of Defendants' egregious misconduct, Mr. Salvo developed prostate cancer. He also developed a lung nodule which may be cancerous and has to be monitored for the foreseeable future. This case seeks compensation for all of Plaintiff's serious injuries, economic damages, emotional distress and pain and suffering.

JURISDICTION AND VENUE

12. Jurisdiction exists under 28 U.S.C. §1332(a), as well as under 28 U.S.C. §1367(a) because Plaintiff and Defendants are citizens of different states and the matter in controversy exceeds the sum of $75,000, exclusive of interest and costs.

13. This Court has personal jurisdiction over each Defendant because each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in this District. Defendants' unlawful conduct has injured persons residing in, located in, or doing business throughout this District.

14. Venue is proper in this Court pursuant to 28 U.S.C. §1391 because Plaintiff resides in this District, many of the acts and transactions giving rise to this action occurred in this District, and because Defendants have intentionally availed themselves of the laws and markets within this District and have conducted substantial business in this District.

PARTIES

15. Plaintiff Steven A. Salvo resides in Essex County, New Jersey. Mr. Salvo ingested Ranitidine, which was prescribed to him and purchased from CVS, at 300 mg. per day, seven days per week for at least five years. As a direct and proximate result of ingesting Ranitidine, Mr. Salvo developed, and was diagnosed with, prostate cancer in January 2020. In addition, in or about early 2021, Mr. Salvo learned of a lung nodule that could be cancerous. Mr. Salvo would not have purchased or ingested Ranitidine if he had known it would expose him to toxic quantities of NDMA. Mr. Salvo incurred, and will continue to incur, expenses, pain, fear, and severe emotional distress as a result of his prostate cancer and possible lung cancer, caused by Ranitidine.

16. Defendant Perrigo Company PLC is a company whose North American base of operations is at 515 Eastern Avenue, Allegan, Michigan. Perrigo Company PLC does substantial business in the State of New Jersey, and is engaged in the manufacturing, distribution, and sale of defective Ranitidine throughout the United States, including New Jersey.

17. Defendant Perrigo Research & Development Company is a corporation organized under the laws of Michigan with a principal place of business at 601 Abbot Road, East Lansing, Michigan 48823. It is the holder of Abbreviated New Drug Application ("ANDA 091429, which is the Ranitidine being sold by CVS. It is a wholly-owned subsidiary of Perrigo Company, PLC. There is a unity of ownership between Perrigo Company PLC and Perrigo Research & Development Company. At all relevant times, Perrigo Research & Development

Company acted as an authorized agent, representative, employee and/or alter ego of Perrigo Company PLC, while performing activities including but not limited to advertising, warranties, dissemination of information and distribution of Ranitidine-containing medications in the United States and New Jersey.

18. Defendant CVS Health Co. is a corporation organized under the laws of the State of Rhode Island and Providence Plantations and maintains its principal place of business at One CVS Drive, Woonsocket, Rhode Island, 02895. Among its services, CVS provides pharmacy services. CVS sold Ranitidin in prescription form, manufactured by Perrigo. CVS dispensed Ranitidine to Mr. Salvo for at least five (5) years. CVS does substantial business in the state of New Jersey.

FACTUAL ALLEGATIONS

19. Mr. Salvo suffers from chronic heartburn.

20. He went to see Doctor Lynette Suarez, in or about 2015, who prescribed Ranitidine for his heartburn. He was told by his doctor to take 300 mg. of Ranitidine daily.

21. Mr. Salvo filled all his prescriptions for Ranitidine at CVS Pharmacy in West Caldwell, New Jersey.

22. In accordance with his physician's instructions, Mr. Salvo ingested Ranitidine daily and continued taking it for at least five years.

23. On or about September 30, 2019, CVS suspended the sale of over-the-counter Zantac, but continued selling prescription Ranitidine. CVS did not inform Mr. Salvo that they had suspended sales of Zantac. Instead, it continued filling his prescriptions for Ranitidine for approximately nine months thereafter.

24. In or about January 2020, Mr. Salvo took a routine blood test to measure the

prostate specific antigen ("PSA") in his blood. It was greatly elevated.

25. Mr. Salvo subsequently underwent a number of other tests, including a painful biopsy, to determine that he had prostate cancer.

26. Mr. Salvo was terrified and overwhelmed by his diagnosis.

27. Mr. Salvo subsequently underwent radiation treatment for his prostate cancer.

28. Mr. Salvo endured pain, suffering, fear and emotional distress in treating his prostate cancer.

29. In or about early 2021, Mr. Salvo was diagnosed with a nodule in his lung. He was advised to monitor the nodule for an indefinite period of time to determine if there are any changes to the nodule, which will indicate it is cancerous.

30. Mr. Salvo is very fearful that the lung nodule will prove to be cancerous. He also fears that his prostate cancer will return, or will spread to a different part of his body.

31. Had Mr. Salvo been informed that taking Ranitidine would expose him to unsafe quantities of NDMA such that it could and did cause him to contract prostate cancer, and possibly lung cancer, or other cancers, he never would have purchased or ingested Ranitidine. Plaintiff required and incurred and will continue to require and incur expenses in connection with medical treatment as a result of these injuries, which were caused by Ranitidine, and Defendants' unlawful conduct concerning Ranitidine's design, manufacture, marketing, and sale. Plaintiff has endured and will continue to endure pain, suffering, mental anguish, and loss of enjoyment of life as a result of his serious injuries, as well as other damages to be proven at trial.

COUNT I
(STRICT PRODUCTS LIABILITY – DESIGN DEFECT)

32. Plaintiff hereby incorporates by reference the allegations contained in the foregoing paragraphs as if fully set forth herein.

33. Defendants manufactured, designed, marketed, distributed, and sold Ranitidine during the period set forth above, with the expectation of reaching consumers such as Plaintiff Steven Salvo.

34. The Ranitidine manufactured, designed, marketed, distributed, and sold by Defendants was defective in design or formulation, because, when it left the hands of Defendants, the foreseeable risks of the product far exceeded the benefits associated with its use, and was far more dangerous than an ordinary consumer would expect.

35. Ranitidine is unreasonably dangerous and unsafe for its intended purpose because, when ingested, it forms extremely high levels of NDMA and other harmful metabolites in the body. NDMA is a human carcinogen associated with various types of cancers. Indeed, the chemical structure of Ranitidine itself is inherently unstable, and contains two chemical precursors to the formation of NDMA: a nitrite group and a dimethylamine (DMA) group.

36. The foreseeable risks of Ranitidine include an increase in the occurrence of cancer from exposure to Ranitidine and NDMA.

37. The fact that harm such as that suffered by Plaintiff would occur from use of Ranitidine was completely foreseeable.

38. The likelihood that cancer would result from the use of Ranitidine is very high. Thus, Defendants knew that the likelihood and severity of the harm associated with Ranitidine usage was great. Upon information and belief, thousands of patients who took Ranitidine, including Plaintiff, experienced cancers proximately caused by Ranitidine use or have been

exposed to an unreasonable risk of developing cancer. The likelihood and severity of the cancers suffered by Plaintiff and other users of Ranitidine far outweighed the Defendants' burden in taking safety measures to reduce or avoid the harm.

39. At the time Defendants manufactured, designed, marketed, distributed, and sold Ranitidine to Plaintiff, safer, more practical, alternative designs were available to treat gastrointestinal conditions such as heartburn, including but not limited to prescription drug alternatives such as Pepcid, Prilosec, Nexium, Prevacid, Protonix, AcipHex, and Dexilant, which pose much less risk of cancer with comparable or adequate efficacy. Indeed, these drugs, which are intended to treat the same conditions as Ranitidine is intended to treat, do not metabolize into NDMA when ingested.

40. The Ranitidine manufactured, designed, marketed, distributed, and sold by Defendants was not unavoidably unsafe, as alternative formulations for these types of medications were available with comparable or adequate efficacy that did not pose the same cancer risk.

41. The risks of NDMA formation in the human body from Ranitidine ingestion, and the concomitant risk of cancers associated with NDMA, were actually known to and foreseeable to all.

42. Even before Ranitidine was commercially launched in 1983 in the United States, the scientific community expressed concern about the propensity of Ranitidine to form NDMA in the body when ingested. Further, from the time of Ranitidine's launch until the present day, various scientific literature expressed concerns about NDMA formation from Ranitidine. Plaintiff was unaware of this scientific literature, but Defendants were aware of it.

43. The Defendants could have reduced or prevented the foreseeable risks of harm associated with Ranitidine by adopting a reasonable and feasible alternative design.

44. The Defendants knew that ordinary patients would use Ranitidine without knowledge of the hazards involved in such use. Ranitidine failed to perform as an ordinary consumer would expect in that it produced hazardous amounts of NDMA and other harmful metabolites when ingested in the body.

45. The benefit in promoting enhanced accountability through strict products liability outweighs the benefit of a product that the Defendants should have and could have made safer years earlier.

46. Had Plaintiff known of the defect in Ranitidine, he would not have taken Ranitidine. Instead, he would have taken a safer alternative to Ranitidine that would not have exposed him to dangerous levels of NDMA.

47. Based on the foregoing, Defendants' Ranitidine was defective in design at the time it left Defendants' control.

48. As a direct and proximate result of the defective design of Ranitidine manufactured by Defendants and ingested by Plaintiff, Plaintiff developed prostate cancer, as well as a possibly cancerous nodule of the lung, and has suffered damages, including but not limited to personal injury, bodily harm, emotional distress, pain and suffering, permanent physical injuries, loss of enjoyment of life, economic and non-economic damages, and will continue to suffer such injuries in the future.

COUNT II
(STRICT LIABILITY – FAILURE TO WARN)

49. Plaintiff hereby incorporates by reference the allegations contained in the foregoing paragraphs as if fully set forth herein.

50. The Ranitidine manufactured, designed, marketed, distributed and sold by Defendants was defective due to inadequate warning or instruction, because at the time it left the

control of Defendants and was supplied to Plaintiff, Defendants knew or should have known that their product was unreasonably dangerous as confirmed by the extensive body of published literature and its own internal data, because Ranitidine substantially and significantly increases the risk of cancer compared to other treatment options for gastrointestinal conditions such as heartburn.

51. Despite the fact that Defendants knew or reasonably should have known about the increased risk of cancer with Ranitidine as compared to other treatment options for heartburn, Defendants failed to exercise reasonable care to adequately warn of the increased cancer risk.

52. Defendants made no reference on the Ranitidine label or inserts to the formation of high quantities of NDMA when ingested in the human body, and that NDMA leads to cancers in animals and humans.

53. Ordinary consumers and physicians would not have recognized, and did not recognize, the risks Ranitidine posed to patients.

54. The Ranitidine manufactured and supplied by Defendants was also defective due to inadequate post-marketing warning or instruction, because after Defendants knew or should have known of the substantially increased risks as described above, Defendants failed to provide adequate post-market or post-approval warnings to consumers and/or their healthcare providers and/or the FDA, which they have authority to do as the holder of the NDAs, and failed to revise the Ranitidine label and insert to warn of the serious and substantially increased risk of cancer caused by Ranitidine. Nor did Defendants warn Plaintiff or his physician or the FDA that alternative safer options were available.

55. Had Defendants adequately warned and instructed Plaintiff, he would not have taken Ranitidine, and would not have developed prostate cancer and, possibly, lung cancer.

Instead, Plaintiff would have taken an alternative drug to Ranitidine that would not have exposed him to harmful levels of NDMA and other dangerous metabolites.

56. Plaintiff's cancer(s) were directly and proximately caused by Defendants' inadequate warnings.

57. As a direct and proximate result of the defective design of Ranitidine manufactured by Defendants and consumed by Plaintiff, Plaintiff suffered serious damages, including but not limited to personal injury, bodily harm, emotional distress, pain and suffering, permanent physical injuries, loss of enjoyment of life, economic and non-economic damages, and will continue to suffer such injuries in the future.

COUNT III
(NEGLIGENCE AND GROSS NEGLIGENCE)

58. Plaintiff incorporates the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

59. Defendants had a duty to exercise ordinary and reasonable care in the design, manufacture, testing, sale, labeling, and/or distribution of Ranitidine they placed into the stream of commerce, including a duty to assure that the product did not cause foreseeable and unreasonable injury.

60. Defendants had and have a duty to monitor the adverse effects associated with their pharmaceutical products, including Ranitidine.

61. Defendants have a continuing duty to warn of the adverse effects associated with their pharmaceutical products, including Ranitidine, to avoid reasonably foreseeable risks.

62. Defendants owed these duties to Plaintiff because it was foreseeable to Defendants that consumers like Plaintiff would ingest and consequently be endangered by Ranitidine.

63. Defendants knew that Ranitidine was likely to form NDMA within the human body in high quantities due to the inherent instability of the Ranitidine molecule, and as a result of such NDMA formation, Ranitidine users would be exposed to unreasonable risks of cancer.

64. Defendants' knowledge that NDMA would be formed within the human body as a result of Ranitidine usage, only grew with each year Ranitidine was on the market.

65. Defendants breached their duty of care to Plaintiff through their negligent acts and willful omissions.

66. Defendants were negligent in the design, manufacture, sale, testing, and/or distribution of Ranitidine in that they: (a) failed to use due care in designing, formulating, developing, testing, manufacturing and selling of Ranitidine so as to avoid or warn against the described risks to consumers who used Ranitidine ; (b) placed an unsafe product into the stream of commerce; and (c) failed to warn of the dangers associated with the use of Ranitidine despite having actual and/or constructive knowledge of such dangers.

67. Defendants failed to use the amount of care in designing Ranitidine that a reasonably careful manufacturer would have used to avoid exposing patients to foreseeable risks of harm.

68. A reasonable manufacturer and seller under the same or similar circumstances would have instructed Plaintiff and Plaintiff's physician on the unsafe qualities of Ranitidine.

69. Defendants' failure to adequately warn Plaintiff and Plaintiff's physician about the dangers of Ranitidine was compounded by the Defendants' omissions to doctors during sales and other promotional activities.

70. Defendants' misconduct constitutes gross negligence.

71. Plaintiff was injured as a direct and proximate result of the Defendants' gross negligence.

72. By designing Ranitidine such that it formed NDMA and other harmful metabolites in the human body following ingestion, when they knew that Ranitidine acted this way and knew about the harmful effects of NDMA, and by intentionally withholding a safer design of Ranitidine, while failing to warn (let alone adequately warn) of the known risks of Ranitidine, Defendants acted in reckless disregard of, or with a lack of substantial concern for, the rights of others.

73. Defendants intentionally designed Ranitidine in the way that they did and withheld the safer designs from patients while in disregard of the known risk of NDMA formation from Ranitidine usage, making it highly probable that harm would result.

74. Defendants knew that their conduct would harm Plaintiff and many others, but chose to withhold any warning to Plaintiff and others, or to utilize a safer design for Ranitidine, simply to make more money for themselves.

75. Each of the foregoing acts or omissions by Defendants, when viewed objectively from its standpoint at the time, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to Plaintiff and others.

76. Defendants acted with conscious indifference to the right, safety, or welfare of Plaintiff and others. Their deceptive and inadequate labeling and marketing, misrepresentation of the risks of Ranitidine to doctors and the general public, and refusal to engage in proper safety evaluation and investigation both before and after Ranitidine was first sold, were undertaken in the callous pursuit of market advantage and without regard for the safety of those exposed to Ranitidine.

COUNT IV
(BREACH OF EXPRESS WARRANTY)

77. Plaintiff hereby incorporates by reference the allegations contained in the foregoing paragraphs as if fully set forth herein.

78. Defendants were merchants and sellers with respect to Ranitidine.

79. In order to induce the purchase and/or use of Ranitidine, Defendants expressly warranted to potential users of Ranitidine that Ranitidine was safely tested and manufactured and was safe for the uses for which it was designed and/or advertised to be used. Express warranties were contained in direct-to-consumer advertising and other promotional and marketing campaigns, Ranitidine product information inserts given to patients with their prescriptions, the product labeling, and other public communications and representations.

80. Defendants breached said warranty in that Ranitidine was not safe to be used for the purposes for which it was manufactured and/or advertised.

81. Plaintiff was seriously injured as a result of detrimental reliance upon Defendants' express warranties.

COUNT V
(BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY)

82. Plaintiff hereby incorporates by reference the allegations contained in the foregoing paragraphs as if fully set forth herein.

83. Defendants were manufacturers and merchant sellers with respect to Ranitidine.

84. An implied warranty of fitness for human consumption and merchantability runs from each Defendant to consumers like Plaintiff.

85. In order to induce the purchase and/or use of Ranitidine, Defendants impliedly warranted to potential users of Ranitidine that Ranitidine was safely tested and manufactured and was safe for the uses for which it was designed and/or advertised to be used.

86. Defendants breached this warranty in that Ranitidine was not safe for the uses for which it was manufactured and/or advertised.

87. Plaintiff relied on the Defendants' skill or judgment to provide a product suitable for this purpose. Defendants are in the business of designing, manufacturing, selling, and marketing prescription drugs and specialize in drugs for the treatment or prevention of heartburn.

88. Defendants had reason to know that Plaintiff and/or his doctors would rely on the Defendants' skill or judgment.

89. Plaintiff developed prostate cancer and a lung nodule, which may be cancerous, as a result of his detrimental reliance upon Defendants' implied warranties.

90. In addition to the common law, the conduct alleged herein constitutes a breach of the implied warranty of merchantability.

COUNT VI
(NEGLIGENT MISREPRESENTATION AND FRAUD)

91. Plaintiff hereby incorporates by reference the allegations contained in the foregoing paragraphs as if fully set forth herein.

92. Defendants manufactured, designed, marketed, labeled, distributed, and sold Ranitidine.

93. Defendants had and have a duty not to deceive consumers and their physicians, including Plaintiff, about Ranitidine.

94. Defendants had a duty to disclose to Plaintiff, his physician, and the public that Ranitidine was not safe for use by Plaintiff due to its carcinogenic effect.

95. Defendants made representations to Plaintiff and his physician regarding the character and/or quality of Ranitidine for guidance in their decision to select Ranitidine for Plaintiff's use.

96. Specifically, Defendants represented that Ranitidine was just as safe as or even safer than other drugs for treatment of gastrointestinal conditions such as heartburn.

97. Defendants knew, or reasonably should have known, that such statements were false.

98. Defendants negligently and/or recklessly misrepresented to Plaintiff, Plaintiff's physician, and the healthcare industry, the safety and effectiveness of Ranitidine and/or recklessly and/or negligently concealed material information, including adverse information, regarding the safety, effectiveness, and dangers posed by Ranitidine.

99. Defendants negligently or recklessly concealed from Plaintiff, Plaintiff's physician, the health care industry, and the consuming public: (a) the defective, improper, negligent, fraudulent, and dangerous design of Ranitidine; (b) the connection between Ranitidine and NDMA formation; (c) that Ranitidine can produce NDMA at harmful levels; (d) that harmful levels of NDMA are carcinogenic; (e) the inadequacy of the labeling for Ranitidine; and (f) the dangerous carcinogenic effects of Ranitidine.

100. Defendants negligently, and/or intentionally misrepresented, this information in Ranitidine's labeling, promotions and advertisements, in order to avoid losses and sustain profits in their sales to consumers and instead labeled, promoted, and advertised their product as just as safe and effective as other heartburn medications.

101. In supplying this false information, Defendants failed to exercise reasonable care or competence in obtaining safety information concerning Ranitidine and in communicating this information to the intended recipients, including Plaintiff and his physician.

102. Defendants should have reasonably known, through the exercise of due care, that these representations were false, and they made the representations without the exercise of due care leading to the deception of Plaintiff, Plaintiff's physician, and the healthcare industry.

103. At all times herein mentioned, neither Plaintiff nor Plaintiff's physician were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had they been aware of said facts, Plaintiff would not have taken Ranitidine, and Plaintiff's physician would not have prescribed Ranitidine. Plaintiff justifiably relied on and/or was induced by Defendants' negligent or reckless misrepresentations and/or negligent or reckless failure to disclose the dangers of Ranitidine and relied on the absence of information regarding the dangers of Ranitidine which Defendants negligently or recklessly suppressed, concealed, or failed to disclose to Plaintiff's detriment.

104. Defendants had a post-sale duty to warn Plaintiff, Plaintiff's physician, and the general public about the potential risks and complications associated with Ranitidine, due to its carcinogenic effect, in a timely manner.

105. Defendants made the representations and actively concealed information about the defects and dangers of Ranitidine with the absence of due care such that Plaintiff's physician and the consuming public would rely on such information, or the absence of information, in selecting Ranitidine as a treatment.

106. Plaintiff reasonably relied to his detriment upon Defendants' representations that Ranitidine was just as safe and effective as other methods of treating and preventing gastrointestinal conditions such as heartburn.

107. Had Plaintiff or his physician known of Defendants' concealment of the true facts – that Ranitidine was more dangerous than other heartburn medications, Plaintiff would not have ingested Ranitidine.

108. As a direct and proximate result of the foregoing concealments and omissions, Plaintiff suffered serious injuries, including cancer.

109. As a direct and proximate result of the foregoing concealments and omissions, Plaintiff requires and/or will require more healthcare and services and did incur medical, health, incidental, and related expenses.

110. Plaintiff will also require additional medical and/or hospital care, attention, and services in the future in connection with his lung nodule, which has to be checked and treated as it may be cancerous.

COUNT VII
(NEW JERSEY PRODUCTS LIABILITY ACT- N.J. STAT. §§ 2A:58C-1 ET SEQ.)

111. Plaintiff hereby incorporates by reference the allegations contained in the foregoing paragraphs as if fully set forth herein.

112. Defendants are strictly liable for the defects in Ranitidine that existed when it left the Defendants' control.

113. Ranitidine was not reasonably fit, suitable or safe for its intended purpose. It failed to contain an adequate warning of a defect that was known or reasonably should have been known to Defendants.

114. At the time Ranitidine left the Defendants' control, there was a practical and technically feasible alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Ranitidine.

115. Ranitidine proximately caused serious injury to Plaintiff, and this serious injury was reasonably foreseeable to Defendants.

COUNT VIII
(BATTERY)

116. Plaintiff hereby incorporates by reference the allegations contained in the foregoing paragraphs as if fully set forth herein.

117. Defendants knew or reasonably should have known that, when ingested, Ranitidine metabolizes and forms high levels of NDMA in the body. During the period of time Defendants manufactured, distributed and sold Ranitidine, it knew Ranitidine formed excessive levels of NDMA in the body.

118. Plaintiff ingested Ranitidine for at least five years, and, as a result, was exposed to excessive amounts of a potent carcinogen, NDMA. Plaintiff's exposure to NDMA was caused directly by Defendants.

119. No reasonable person would want to be subjected to excessive levels of a potent carcinogen, and thus, Plaintiff's exposure to NDMA constituted an offensive contact caused by Defendants.

120. Although Plaintiff voluntarily ingested Ranitidine, at no time did Plaintiff know that Ranitidine ingestion resulted in the formation of excessive levels of NDMA in the body. If Plaintiff had known this, he would not have taken Ranitidine. Therefore, Plaintiff never consented, implicitly or explicitly, to ingesting a substance that would cause large amounts of NDMA to be formed in his body.

121. Defendants' battery upon Plaintiff proximately caused his serious injuries and damages for which recovery is sought.

COUNT IX
(MEDICAL MONITORING)

122. Plaintiff hereby incorporates by reference the allegations contained in the foregoing paragraphs as if fully set forth herein.

123. As alleged above, when ingested, Ranitidine metabolizes into NDMA and other harmful metabolites in the body. NDMA is classified as a probable human carcinogen by most, if not all, regulatory agencies around the world, including the FDA and EPA.

124. Cancer may have a latency period of many years, and may take years to manifest. Plaintiff is at an increased risk of developing cancer as he ingested Ranitidine in quantities (300 mg daily), and over a period of time (at least five years) that caused him to be exposed to NDMA in dangerous levels.

125. Plaintiff has already developed prostate cancer as a result of his exposure to Ranitidine, and may also have lung cancer as a result of his exposure to Ranitidine. Plaintiff is, also, at heightened risk of developing future cancers, or a recurrence of cancer.

126. Cancer is a serious life-threatening illness and debilitating cellular, genetic, and physical injury. Technology, analytical tools, tests, and/or monitoring procedures exist and are readily available to provide for the testing and early detection of cancer in patients. These technologies, tools, tests, and/or monitoring procedures are accepted and widely used by the scientific and medical community.

127. Early detection of cancer in patients is one of the best, and sometimes the only means to treat cancer such that it does not cause lasting, permanent injury, illness, or death.

128. The tests and treatments for the early detection and treatment of cancer must be prescribed by a qualified physician, and are conducted according to the latest, contemporary, and widely accepted scientific principles. Because NDMA-associated cancer screenings may not be conducted with the frequency necessary to identify cancer in the absence of exposure to NDMA, the prescribed monitoring regime is different from that normally recommended in the absence of exposure. Plaintiff requires more frequent screenings not within the purview of routine medical exams.

129. Plaintiff is entitled to compensatory damages and monetary relief for the cost of medical monitoring procedures over the rest of his life.

COUNT X
(PUNITIVE DAMAGES)

130. Plaintiff hereby incorporates by reference the allegations contained in the foregoing paragraphs as if fully set forth herein.

131. Defendants' conduct as alleged in this Complaint shows that Defendants acted maliciously, with aggravated or egregious fraud, and intentionally disregarded Plaintiff's rights, so as to warrant the imposition of punitive damages.

132. As a direct and proximate result of Defendants' malicious, fraudulent, and intentional disregard of Plaintiff's rights, Plaintiff is entitled to punitive damages to punish Defendants and deter similar wrongdoing by others in the future.

WHEREFORE, Plaintiff demands the following relief, jointly and severally, against all Defendants, as follows:

(a) Compensatory economic and non-economic damages, special damages, consequential and general damages, including pain and suffering, and emotional distress, in an amount to be supported by the evidence at trial;

(b) Exemplary and punitive damages sufficient to punish Defendants for the acts complained of herein and to deter Defendants and others from future wrongful practices, in an amount to be determined by a jury;

(c) An award of reasonable attorneys' fees, court costs, and other litigation expenses;

(d) Prejudgment interest and post-judgment interest;

(e) A contingency claim multiplier, and an award to reflect negative tax consequences of a lump sum jury award; and

(f) Such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff Steven A. Salvo hereby demands a trial by jury on all issues so triable.

Dated: August 9, 2021

THE SALVO LAW FIRM, PC

By: /s/ Cindy D. Salvo
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